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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,205	01/12/2001	Ralf Zielenski	RDID0013US	2666

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Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,205

Applicant(s)

ZIELENSKI, RALF

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed July 6, 2004 has been received and entered into the case. Claim 54 is canceled. Claims 18, 20, 22 and 23 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, first paragraph, have been withdrawn due to amendment.

Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama.

Applicant claims an aqueous solution comprising (a) NAD or NADP and derivatives thereof; (b) citric acid or citrate salts (c) nitrogen compounds with a specified formula; wherein the composition remains unchanged for 15 months at about 2 – 8C. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2 – 300 mM.

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Aoyama teaches reagent compositions comprising 0.1 – 50 mM hydroxylamines of the claimed formula (abstract, col.2-3,7), citrate buffers and NAD or NADP (col.6).

Although Aoyama does not specifically disclose a composition comprising the claimed components, one in the art is able to “at once envisage” the specific combination within the generic composition. In addition, while Aoyama does not specifically identify that the composition is stable after 15 months at 2 – 8C, such an attribute is inherent to the reference composition. Moreover, the claimed function of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the function is not limiting.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama.

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Applicant claims an aqueous solution comprising (a) NAD or NADP and derivatives thereof; (b) citric acid or citrate salts (c) nitrogen compounds with a specified formula; wherein the composition remains unchanged for 15 months at about 2 – 8C. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2 – 300 mM and the citric acid is present at 5 – 200 mM.

Aoyama teaches reagent compositions comprising 0.1 – 50 mM hydroxylamines of the claimed formula (abstract, col.2-3,7), citrate buffers and NAD or NADP (col.6).

Although Aoyama does not specifically disclose a composition comprising the claimed components, one in the art is able to “at once envisage” the specific combination within the generic composition. In addition, while Aoyama does not specifically identify that the composition is stable after 15 months at 2 – 8C, such an attribute is inherent to the reference composition. Moreover, the claimed function of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the function is not limiting.

Aoyama does not teach the composition comprising 5 – 200 mM citrate. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amount of citrate buffers as a matter of routine experimentation, and as demonstrated by the examples of Aoyama. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and

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Aoyama to optimize the amount of citrate buffer in the composition of Aoyama, with a reasonable expectation for successfully obtaining the effective reagent composition of Aoyama.

Response to Arguments

Applicant argues that Aoyama does not teach the composition is unchanged after 15 months of storage at 2 – 8C and points to examples that only retain 90% activity.

However, this argument fails to persuade because Aoyama clearly teaches the claimed composition with the claimed amounts of hydroxylamine. As such, the composition of Aoyama must inherently exhibit the claimed functional traits, since the compositions are the same. It is noted that applicant exemplifies “qualitatively unchanged” to mean stable (spec, p.6), thus does not necessarily require the composition to be at 100% effect. Absent evidence of unexpected results in the claimed composition, one of ordinary skill in the art would certainly have been motivated by routine practice and Aoyama to optimize the amounts of active ingredients of Aoyama, with a reasonable expectation for successfully obtaining an effective and stable composition. Therefore, the claims stand rejected.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
September 2, 2004
AU 1651



LEON B. LANKFORD, JR.
PRIMARY EXAMINER